



ISSN 2456-3110

Vol 5 · Issue 4

July-Aug 2020

Journal of
**Ayurveda and Integrated
Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Charaka
Publications

Indexed

A comparative clinical study on *Madhusiktadi Lepa* with and without *Siravyadha* in the management of *Padadari*

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ABSTRACT

Movement is one of the important gifts of God to mankind. If the individual has proper movements then it is indicative of undisturbed health. In some disorders foot movement are impaired; Crack foot syndrome is one such disorder where the person is apparently healthy but unable to walk because of pain, bleeding coupled with itching. In *Ayurveda*, it is referred as *Padadari*. The disease involves the *Vatadosha* leading to dryness, cracks, and fissures. The symptoms may include *Vedana*, *Kandu*, *Daha*, *Raktasrava*. So, in case of *Padadari* Acharyas' explained *Snehan*, *Swedan*, *Siravyadha* followed by *Lepa* are advised as line of treatment. So, in this study two modalities viz. *Siravyadha* and *Lepa* are selected. The study was carried out on 60 patients. These patients were divided into two groups A & B each of 30 patients. Group A patients received *Madhusiktadi Lepa* and group B received *Siravyadha* with *Madhusiktadi Lepa*. Considering thorough statistical analysis of various study parameters and patient responses to the treatment, it is observed that Group B treatment has shown relatively better performance than group A treatment. Group B treatment has shown 53.26% patients completely cured (76-100% cure) and 46.66% patients shown marked improvement which is between 51-75% cure. Whereas group A treatment has shown 39.9 % patients were completely cured (76-100% cure) and 60.0% marked improvement (51-75% cure).

Key words: *Padadari*, *Madhusiktadi Lepa*, *Siravyadha*, *Kshudra Roga*, *Marma*.

INTRODUCTION

The *Padadari* disease is characterized by mild to severe forms of cracks, which are seen in the foot, more common on the heel. Cracked heels (also known

as heel fissures) can cause the skin area to become dry, rough and irritated. As cracks form on the sides or bottom of the skin on the heel area, the problem can be even worse when a callus is present. Suitable reference for the problem can be found out in *Kshudra Roga* in Ayurvedic classics. Sushruta has explained it under *Kshudra Roga*. Even though it is mentioned as a *Kshudra Roga*, it will produce lot of discomfort to the sufferer demanding more complex treatment modalities. Locomotion is the commonest and basic physical need or activity, which is carried out throughout the life. *Padadari* is one such skin disease of the feet affecting mainly sole. Excessive walking and dryness of *Pada Charma* will lead to *Padadari*.^[1]

Kshudra Roga as refer to simple diseases having simple etiology and symptoms. But the negligence by the patient or by the treating physician makes the

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Submission Date: 16/07/2020

Accepted Date: 20/08/2020

Access this article online

Quick Response Code



Website: www.jaims.in

DOI: 10.21760/jaims.5.4.9

condition worse and patient may ultimately made to suffer heavily compromising walking. The fissures may deepen causing extension of symptoms or complicating the condition.

In this modern era people expect to have quick, easy, economical and effective treatment without affecting their day to day routine. *Siravyadha* is done to expel the vitiated *Raktha* from the site and provide relief. This method is considered to be the effective, quick, and economical. *Siravyadha*^[2] is also accepted as half of the therapeutic measure in *Shalyatantra* like *Vasti* in *Kayachikitsa*.

The external application of some suitable drug is clearly a rational method of treatment, and even when the cause lies deep, external applications are often of value in moderating the symptoms of the diseases. *Lepa* is one of the important procedures of Ayurveda which is commonly used to treat many diseases. In *Susruta Samhita*, *Chikitsa*^[3] of *Padadari* includes *Siravyadha*, *Snehana*, *Swedana* and application of *Lepa*. *Lepa* consist of *Madhuchista*, *Vasa*, *Majja*, *Sarja Nirayasa*, *Gairika*, *Yavakshara*, *Ghruta* in the form of local application. Local therapeutic procedure which is found to be highly efficacious in skin disorders to reduce the local discomfort which is by easy and fast absorption and to reduce unwanted reactions.

Madhusiktadi Lepa^[4] is one such formulation explained by *Acharya Vangasena*. The ingredients are expected to be helpful in alleviating symptoms of *Padadari* and cure the disease. This *Lepa* will be applied over an area where cracks are present. This is considered to be easy, patient friendly and safe method.

In the clinical study, importance was given to theoretical, practical and clinical point of view in systematic and scientific way with both ancient and modern literature. Patient having *Padadari* were mainly from the middle age and working class. It was due to poor hygiene of foot and excess walking without footwear. In *Padadari* symptoms like *Daha*, *Kandu*, bleeding is present which are not mentioned in Ayurvedic text.

The present study was carried out on 60 patients. These patients were divided into two Groups of 30 patients each.

In group A, Patients received *Madhusiktadi Lepa*.

In group B, Patients received *Siravyadha* with *Madhusiktadi Lepa*.

Madhusiktadi Lepa mainly possesses *Vedana* *Sthapaka*, *Vrana Shodhaka*, *Vrana Ropaka* and *Sandhaniya* properties. *Dosha* of *Padadari* is *Vata* and *Dushya* of *Padadari* is *Rasa (Twak)*, *Rakta*, *Mamsa*. So *Raktamokshana* can be done only if *Vata* gets vitiated in *Twak*, *Mamsa*, *Rakta* and *Sira*.

Siravyadha is the puncturing of vein. In *Shalya Tantra* *Raktamokshana* is considered as half the treatment just like *Vasti* is in *Kaya Chikitsa*. *Siravyadha* procedure destroys the *Raktajavikara* from its roots, just as when the bunds of a field are broken, the crop of paddy etc. gets completely destroyed. Blood letting in dorsal venous arch will improve venous drainage; concurrently local tissue metabolism is improved. According to *Bhavaprakasha* of *Bhavamishra*, *Siravyadha* is made and blood is let out. Lubricants like oil or ghee are applied and hot fomentations are given. Application of *Lepa* prepared with *Madhusikta*, *Vasa*, *Shalanirayasa*, *Gairika*, *Kshara* & *Ghruta*. *Siravyadha* with *Madhusiktadi Lepa* therapy to give better results. It is very simple and economical procedure. The symptoms cured completely it does not needed much preparation. Satisfaction of patients is more and there is no much complications also.

MATERIALS AND METHODS

The sources of the data for the entire study are divided into three groups.

- Literary Data collected from *Ayurvedic Samhitas*, modern medical books of surgery, internet sources.
- Drug related data obtained by market and authenticated by Department of *Dravyaguna* & *Madhusiktadi Lepa* was prepared in the Pharmacy of BLDEA's AVS, Ayurveda Mahavidyalaya Hospital & Research Center, Vijayapur.

- Clinical Data gathered from all diagnosed cases of *Padadari* were the samples of present clinical trial. Sampling unit source list was selected from out-patient & in-patient departments of BLDEA'S AVS AMV & Hospital, Vijayapur and through various camps conducted by BLDEA'S AVS AMV & Hospital in and around Vijayapur city. The nature of selected sample was homogenous. So, a group of 60 patients were selected from prepared list those fulfilled the inclusion criteria.

Inclusion Criteria

- Patients within the age group of 17-60 years.
- Patients presenting with classical signs & symptoms of *Padadari*.
- Patients would be selected randomly irrespective of sex.

Exclusion Criteria

- Patient with associated systemic disorders like Diabetes Mellitus, Hypertension are excluded.
- Patient with infectious disorders like HIV, Hepatitis B, Tuberculosis are excluded.
- *Siravyadha Ayogya* were excluded.
- Foot ulcer and any other local dermal lesions.

Sampling Method

All the 60 patients were selected on the basis of simple randomised sampling method. They were divided into two groups A and B of 30 patients each.

- **Group A:** Patients were treated by *Madhusiktadi Lepa*.
- **Group B:** Patients were treated by *Madhusiktadi Lepa* with *Siravyadha*.

Approach to Clinical Study

The enrolled patients according to the selection criteria were thoroughly examined and properly diagnosed after subjecting them for lab investigation (Hb%, RBS, CT, BT, Tri-Dot & HBsAg) and later registered for the study. A case sheet proforma was prepared accordingly. A written consent was taken

from all patients to observe their willingness for the study.

Method of therapy

Two different methods were adopted for two groups that was Group A and Group B to know their individual and relatives' efficacies.

Treatment Pattern

Group A patients were treated with *Madhusiktadi Lepa* daily once in the *Padatala* for 15 days. The method of application of *Lepa* was divided into three main sections.

- *Poorvakarma* included preparing *Lepa* to be ready to apply, procedure was made known to patient in advance and written consent was obtained, followed by cleaning the foot and comforting the patient for the further procedure.
- In *Pradhankarma Madhusiktadi Lepa* was applied as mentioned in *Sharangdhara Uttara Khanda*^[5] evenly over the affected area with sufficient quantity in the morning and kept for 1 hour.
- *Paschatkarma* followed by washing the foot with lukewarm plain water thoroughly.

For group B patients, *Siravyadha Vidhi*^[6] procedure was followed on site of *Siravyadha*^[7] Accordingly, *Siravyadha* was performed on vein 2 *Angula* above the *Kshipra Marma* once on the first day followed by application of *Madhusiktadi Lepa* daily once in the *Padatala* for 15 days. The procedure again followed three main sections.

- *Poorvakarma* included understanding the procedure to patient in advance and taking written consent. *Yavagupaana* - Patients were advised to consume sufficient quantity of *Tila Yavagu 1 Moohurth Kala* (48 minutes), before undergoing *Siravyadhana*. *Abhyanga* and *Sweda* - The affected limb was anointed with *Tila Taila*, followed by *Sthanika Nadi Sweda* with water.
- In *Pradhana Karma* patient was made to sit comfortably over the examination table in the minor OT. Then the area (Prominent vein just 2

Angula above Kshipramarma) was thoroughly cleansed with surgical spirit. A tourniquet was tied 2 inch above the ankle joint to make the vein prominent and if essential, mild blow was given over the vein. A sterile needle of 18 No. gauge was used for Bloodletting, and blood was collected in the measuring jar, the procedure was completed when Blood flow stopped on its own, or up to 200 ml.

- Paschat Karma included letting out blood, the needle was taken out, and the area wiped with cotton swab, a sterile cotton pad was applied and bandaged. The patient was asked to take rest for 10-15 minutes, was also advised to remove the bandage in the evening.

Follow up study

A follow up study for group A and B was carried out for 30 days, mainly on 7th, 15th, 30th day.

Grading & Grouping

Grading & grouping to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the patients in the clinical study. And finally, the assessment as a whole was presented in percent value.

Statistical Assessment

In order to present the study in a scientific manner, the statistical assessment of the result, mean, S.D. & S.E. of each parameter in respect to their values were presented both before & after treatment. These values were considered & compared by using the Chi square test, Mann Whitney U test, Friedman test to obtain the test of significance to know the effectiveness of the both groups.

Criteria for assessment of treatment

Assessment of treatment before and after treatment was based on pain, itching, bleeding, Number of Cracks, Size of Cracks. The assessment was done to evaluate the improvements of Padadari Chikitsa with reference to the signs and symptoms presented at the

end of each observation results obtained after the treatment and was categorized as following:

1. Complete cure : 76-100% relief in signs and symptoms
2. Marked improvement: 51-75% relief in signs and symptoms
3. Moderate improvement: 26-50% relief in signs and symptoms
4. Unchanged : 0-25% relief in signs and symptoms

DISCUSSION

As discussed in the methodology section, patients were divided into two groups each of N=30 in size. The observations were compiled using master chart which was prepared by the follow-up meetings with the patients. Total 5 symptoms of Padadari namely Ruja (pain), bleeding, Kandu (itching), number of cracks and size of cracks were considered for the results and discussion. To understand the effect of both treatments, well accepted scientific statistical tools such as Friedman test to analyze the effect of treatment within the groups, POST HOC study for analyzing the test results, Mann Whiney U test for comparing the improvements between the groups. Group A and B results are compiled in table 1 and 2 respectively.

Table 1: Observations and Result in Group A

S N	Observations	Mean		POST HOC analysis	Friedman Test	P
		BT	AT	Improvement (%)	F	
1.	Ruja	1.63±0.61	0.2±4.1	87.7	69.4	<0.0001
2.	Bleeding	0.63±0.49	0.0	100	46.8	<0.0001
3.	Kandu	0.66±0.61	0.03±0.18	95.4	42.9	<0.0001
4.	No. of cracks	2.26±0.45	0.73±0.45	67.7	83.3	<0.0001

5.	Size of cracks	1.63±0.4	0.77±0.50	52.7	68.3	<0.0001
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Table 2: Observations and Result in Group B

S N	Observations	Mean		POST HOC Study	Friedman Test	P
		BT	AT	Improvement (%)	F	
1.	Ruja	1.5±0.51	1.0±0.31	33.33	29.5	<0.0001
2.	Bleeding	0.73±0.63	0.0	100	46.9	<0.0001
3.	Kandu	0.7±0.67	0.0	100	46.6	<0.0001
4.	No. of cracks	2.47±0.51	0.63±0.66	74.5	81.9	<0.0001
5.	Size of cracks	1.67±0.47	0.46±0.50	72.5	78.9	<0.0001

The tables above showed only BT-before treatment and AT-after treatments for effective analysis. To know the systematic improvement in all 5 symptoms the follow-ups are divided into BT, 7th day, 15th day and 30th day (AT). Following graphs shows the comparison of treatments between the groups for all the follow-ups.

Figure 1: Effect of treatment on Ruja (pain)

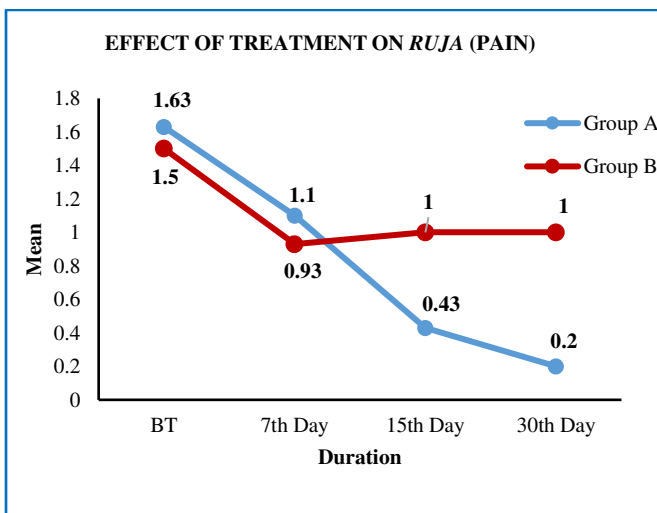


Figure 2: Effect of treatment on Bleeding

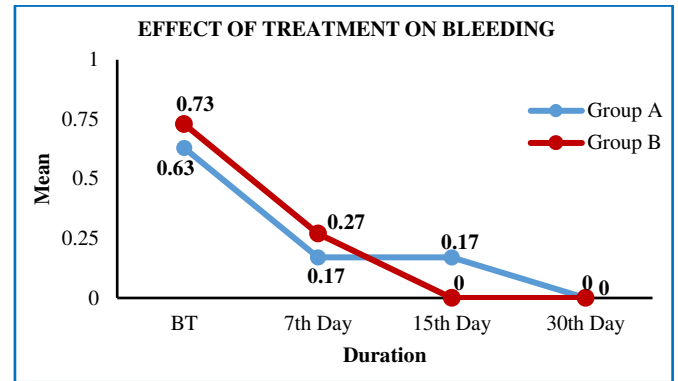


Figure 3: Effect of treatment on Kandu (itching)

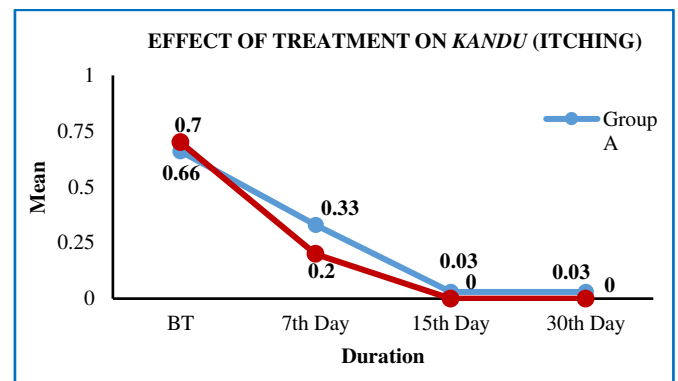


Figure 4: Effect of treatment on number of cracks

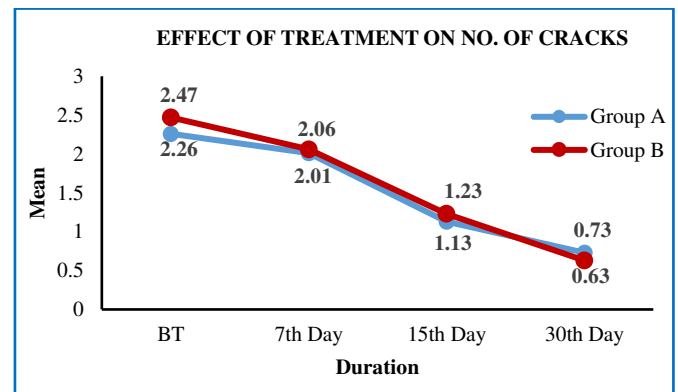
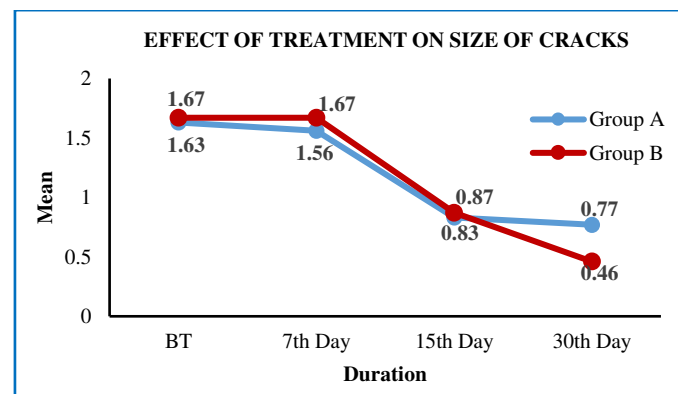
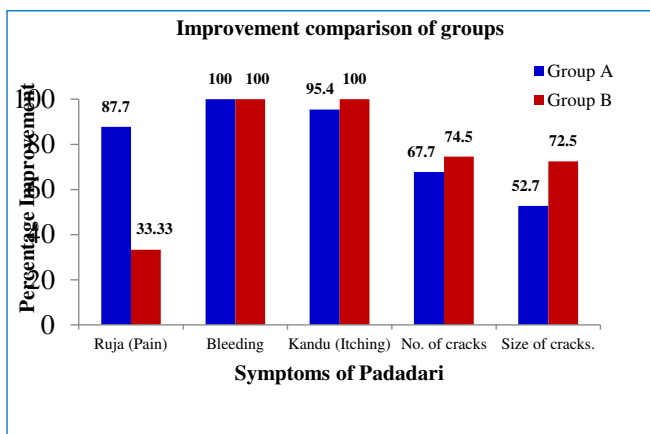


Figure 5: Effect of treatment on size of cracks



From the data analysis it can be clearly observed that, group B treatment i.e. *Siravyada* followed by *Madhusiktadi Lepa* was giving better results. Following figure 6 shows the comparison of percentage improvement of all the symptoms between the groups. It is observed that, except pain for all other symptoms group B treatment showed higher improvement as compared to group A. It is because of more aged person and patients with excess weight were present in group B.

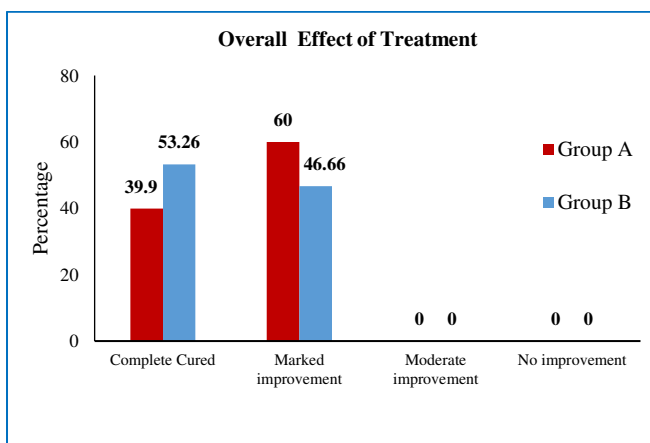
Figure 6: Improvement in symptoms comparison of groups



Discussion on overall response

Considering thorough statistical analysis of various study parameters and patient responses to the treatment, it is observed that Group B treatment has shown relatively better performance than group A treatment. Following figure 7 shows the overall effect of treatment.

Figure 7: Overall effect of treatment



Group B treatment has shown 53.26% patients completely cured (76-100%) and 46.66% patients shown marked improvement which is between 51-75% of the cure. Whereas group A treatment has witnessed 39.9% of completely cured patients and 60% of patients showed marked improvement which lie between is 51-75% cure class. There were no patients left who showed moderate improvement or no improvement. This observation is very much satisfactory in curing the *Padadari* symptoms.

CONCLUSION

The systematic study has been conducted to find out the effective treatment for the treatment of *Padadari*. Patients were divided into two groups A and B to understand the effect of *Madhusiktadi Lepa* and *Siravyada* followed by *Madhusiktadi Lepa* respectively. From the statistical analysis of all 60 patients it can be concluded that, *Padadari* can be very effectively treated by group B treatment i.e. *Siravyada* followed by *Madhusiktadi Lepa*. These outcomes matches with literature *Sushruta Samhita Sharirasthana*^[8] - An act of vain puncture, properly performed, gives more speedy relief than that derived from the *Snehadi* and *Lepa* alone. However, in future the study can be extended to larger number of patients and to longer time treatments to draw the concrete conclusion on the treatment.

ACKNOWLEDGEMENT

Authors would like to thank the management of BLDEA’s AVS Ayurveda Mahavidyalaya Vijayapura and Pharmacy of BLDEA’s AVS, Ayurveda Mahavidyalaya Hospital & Research Center, Vijayapur.

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How to cite this article: Varsha M. Bhiradi, Prasadshakti G. Gannur, N.B.Mashetti. A comparative clinical study on Madhusiktadi Lepa with and without Siravyadha in the management of Padadari. J Ayurveda Integr Med Sci 2020;4:50-56.
<http://dx.doi.org/10.21760/jaims.5.4.9>

Source of Support: Nil, **Conflict of Interest:** None declared.
